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PTO/SB/21 (09-04)

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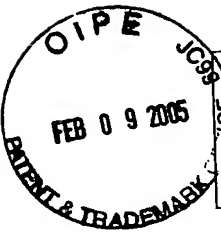
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<b>TRANSMITTAL FORM</b>  (to be used for all correspondence after initial filing)	Application Number	10/650326
	Filing Date	August 28, 2003
	First Named Inventor	Keith A. Hruska
	Art Unit	1614
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	JJJ-P01-599
Total Number of Pages in This Submission	9	

ENCLOSURES (Check all that apply)		
<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Reply to Missing Parts/Incomplete Application <input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD	<input type="checkbox"/> After Allowance Communication to TC <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): Copy of references BA-BE and CA-CL1 Return Receipt Postcard
<div>Remarks</div>		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT			
Firm Name	ROPES & GRAY LLP		
Signature			
Printed name	Ignacio Perez de la Cruz		
Date	February 9, 2005	Reg. No.	55,535

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Dated: February 9, 2005 Signature: Linda Blake  
(Linda Blake)

Docket No.: JJJ-P01-599  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Hruska et al.  
  
Application No.: 10/650326  
  
Filed: August 28, 2003  
  
For: CONJOINT ADMINISTRATION OF  
MORPHOGENS AND ACE INHIBITORS IN  
TREATMENT OF CHRONIC RENAL  
FAILURE

Confirmation No.: 6882  
  
Art Unit: 1614  
  
Examiner: Not yet assigned  
  
February 9, 2005

**INFORMATION DISCLOSURE STATEMENT (IDS)**

MS Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed before the mailing date of a first Office Action on the merits as far as is known to the undersigned (37 CFR 1.97(b)(3)).

A copy of each reference on the PTO/SB/08 is attached, except the U.S. patents.

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure statement shall not be construed to be an admission that any patent,

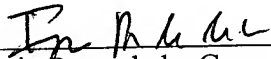
publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 18-1945, under Order No. JJJ-P01-599. A duplicate copy of this paper is enclosed.

Dated: February 9, 2005

Respectfully submitted,

By   
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<b>Substitute for form 1449A/B/PTO</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)			<b>Complete if Known</b>		
			Application Number	10/650326	
			Filing Date	August 28, 2003	
			First Named Inventor	Keith A. Hruska	
			Art Unit	1614	
			Examiner Name	Not Yet Assigned	
Sheet	1	of	3	Attorney Docket Number	JJJ-P01-599

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	AA	US-5,011,691	04-30-1992	Oppermann et al.	
	AB	US-5,266,683	11-30-1993	Oppermann et al.	
	AC	US-4,968,590	11-06-1990	Kuberasampath et al.	
	AD	US-5,723,441	03-03-1998	Higley et al.	
	AE	US-5,849,686	12-15-1998	Kuberasampath et al.	
	AF	US-5,879,908	03-09-1999	Laping et al.	
	AG	US-5,733,441	03-03-1998	Higley et al.	
	AH	US-6,120,760	09-19-2000	Hotten et al.	
	AI	US-6,498,142	12-24-2002	Sampath et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
	BA	WO 92/15223	10-17-1991	Amgen Inc.		
	BB	WO 93/04692	03-18-1993	Creative Biomolecules, Inc.		
	BC	WO 94/03200	02-17-1994	Creative Biomolecules, Inc.		
	BD	WO 98/50060	11-12-1998	Creative Biomolecules, Inc.		
	BE	WO 97/41880	11-13-1997	Creative Biomolecules, Inc.		

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NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>	
	CA	VUKICEVIC et al., "Developing Human Lung and Kidney are Major Sites for Synthesis of Bone Morphogenetic Protein-3 (Osteogenin)", (1994), J. Histochem. Cytochem. 42:869-875		
	CB	JONES, et al., "Involvement of Bone Morphogenetic Protein-4 (BMP-4) and Vgr-1 in morphogenesis and neurogenesis in the mouse", (1991) Development 111: 531-542		
	CC	VUKICEVIC, et al., "Localization of Osteogenic Protein-1 (Bone Morphogenetic Protein-7) During Human Embryonic Development: High Affinity Binding to Basement Membranes", (1994) Biochem. Biophys. Res. Commun. 198: 693-700		
	CD	OZKAYNAK, et al. (1992) "Osteogenic Protein-2 A New Member of the Transforming Growth Factor- $\beta$ Superfamily Expressed Early in Embryogenesis", J. Biol. Chem. 267: 25220-25227)		
	CE	OZKAYNAK, et al., "Murine Osteogenic Protein (OP-1): High Levels of mRNA in Kidney", (1991) Biochem. Biophys. Res. Commun. 179: 116-123.		
Examiner Signature			Date Considered	

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			Art Unit	1614	
			Examiner Name	Not Yet Assigned	
Sheet	2	of	3	Attorney Docket Number	JJJ-P01-599

CF	HRUSKA, K.A., et al., 2000. "Osteogenic protein-1 (OP-1) prevents renal fibrogenesis associated with ureteral obstruction", Am J Phys (Renal) 279:F130-F143
CG	LUO, G., et al., 1995. "BMP-7 is an inducer of nephrogenesis, and is also required for eye development and skeletal patterning" Genes Dev. 9:2808-2820.
CH	DUDLEY, A.T., et al., 1995. "A requirement for bone morphogenetic protein-7 during development of the mammalian kidney and eye". Genes Dev 9:2795-2807
CI	VUKICEVIC, S. et al., 1996. "Induction of nephrogenic mesenchyme by osteogenic protein 1 (bone morphogenetic protein 7)" Proc. Natl. Acad. Sci. U.S.A. 93:9021-9026
CJ	KISPERT A., et al., 1998 "Wnt-4 is a mesenchymal signal for epithelial transformation of metanephric mesenchyme in the developing kidney", Development 125:4225-4234.
CK	SIMON, M., et al., 1999. "Expression of bone morphogenetic protein-7 mRNA in normal and ischemic adult rat kidney", Amer.J.Physiol. 276:F382-F389
CL	VUKICEVIC, S. et al., 1998. "Osteogenic protein-1 (Bone 30 morphogenetic protein-7) reduces severity of injury after ischemic acute renal failure in rat", J.Clin.Invest. 102:202-214.
CM	SURENDRAN, K., et al., 2002. "A role for Wnt-4 in renal fibrosis. Am J Physiol Renal Physiol", 282:F431-F441.
CN	SASSY-PRIGENT et al., 1995. "Morphometric detection of incipient glomerular lesions in diabetic nephropathy in rats", Lab Invest 73:64-71
CO	GOULD, S.E., et al., 2002 "BMP-7 regulates chemokine, cytokine, and hemodynamic gene expression in proximal tubule cells", Kidney International 61:51-60
CP	YAMAMOTO, T. et al., 1993. "Expression of transforming growth factor $\beta$ is elevated in human and experimental diabetic nephropathy" Proc.Natl.Acad.Sci.U.S.A. 90:1814-1818
CQ	MORRISSEY, J., et al., 2002. "Bone morphogenetic protein-7 improves renal fibrosis and accelerates the return of renal function" J.Am.Soc.Nephrol. 13:S14-S21.
CR	IWANO, M., et al., 2002. "Evidence that fibroblasts derive from epithelium during tissue fibrosis", J.Clin.Invest. 110:341-350
CS	HILL, C., et al., 2000. "The renal expression of transforming growth factor- $\beta$ isoforms and their receptors in acute and chronic experimental diabetes in rats", Endocrinology 141:1196-1208
CT	WANG, S. et al., 2001. "Loss of tubular bone morphogenetic protein-7 in diabetic nephropathy", J.Am.Soc.Nephrol. 12:2392-2399
CU	BRENNER et al. 1994 "Chronic Renal Failure" In Harrison's Principles of Internal Medicine, 13 <sup>th</sup> Edition, Isselbacher et al. (eds.), McGraw-Hill, Inc. New York pp. 1274-1281
CV	GLASSOCK et al 1994 "Immunopathogenic Mechanisms of Renal Injury". In Harrison's Principles of Internal Medicine, 13 <sup>th</sup> Edition, Isselbacher et al. (eds.) McGraw-Hill, Inc. New York pp. 1292-1295
CW	BOWIE et al. Deciphering the message in protein sequences: tolerance to amino acid substitutions. Science, (1990 March) 247(4948) 1306-10.
CX	KEES-FOLTS et al. Relationship between hyperlipidemia, lipid mediators, and progressive glomerulosclerosis in the nephrotic syndrome, American Journal of Nephrology (1993) 13(5)365-75
CY	COE et al. "Approach to the patient with diseases of the kidney and urinary tract", Chapter 237, Harrison's Principles of Internal Medicine, 13 <sup>th</sup> ed. Isselbacher et al (eds). New York, McGraw-Hill, p 1252, 1994
CZ	GLASSOCK, R.J. "Immunosuppressive treatment in the prevention of renal failure in primary glomerular diseases", Clinical and Experimental Dialysis and Apheresis, (1981) 5 (1-2) 21-46

Examiner Signature		Date Considered	
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CA1	CARPENTER et al., "Dialysis and transplantation in the treatment of renal failure", Chapter 238, Harrison's Principles of Internal Medicine, 13 <sup>th</sup> ed. Isselbacher et al. (eds). New York, McGraw-Hill, page 1281, 1994	
CB1	TOLINS et al, "Mechanisms of hypertensive glomerular injury", American Journal of Cardiology (1988 Oct 5) 62 911) 54G-58G	
CC1	PONTICELLI et al. "Conventional treatment of idiopathic nephrotic syndrome and membranous nephropathy in adults", Clinical Nephrology (1991) 35 Suppl 1 S16-21	
CD1	KLAHR et al, "The progression of renal disease", <i>N Engl J. Med</i> , 1988 June 23; 318(25): 1657-66	
CE1	WATANABE et al, "Production of hydrogen peroxide by neutrophilic polymorphonuclear leukocytes in patients with diabetic nephropathy", Journal of Clinical Laboratory Analysis", (1993) 7 (4) 209-13	
CF1	HIRSCHBERG, et al., "Effects of insulin-like growth factor I on renal function in normal men", (1993) <i>Kidney Intl.</i> 43:387-397	
CG1	BARD et al., "Towards a genetic basis for kidney development", (1994) <i>Mech. Development</i> 48: 3-11	
CH1	SAMPATH et al., "Dissociative extraction and reconstitution of extracellular matrix components involved in local bone differentiation", (1981), <i>Proc. Natl. Acad. Sci. USA</i> 78: 7599-7603	
CI1	WANG et al. (2003) Bone morphogenic protein-7 (BMP-7), a novel therapy for diabetic nephropathy. <i>Kidney Int.</i> ;63(6):2037-49	
CJ1	YANG et al. (Aug. 1998) Local macrophage and myofibroblast proliferation in progressive renal injury in the rat remnant kidney, <i>Nephrology, Dialysis, Transplantation</i> ,13 (8) 1967-74	
CK1	FLOEGE et al. (Apr 1992) Glomerular cells, extracellular matrix accumulation, and the development of glomerulosclerosis in the remnant kidney model, <i>Laboratory Investigation</i> , 66(4)	
CL1	SCHILLER et al. (March 1997) Focal glomerulosclerosis in the remnant kidney model-an inflammatory disease mediated by cytokines, <i>Nephrology, Dialysis, Transplantation</i> , 12(3), 430-7	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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IDS (Citation) by Applicant (3 pages) (43 references)